REMARKS

Claims 1 to 15 are under consideration. Claim 1, 11 and 15 (and dependent claims there from) have been amended. Reconsideration of all claims 1 to 15 is requested.

Claim Rejections- 35 USC "§ 103

Claims 1-15 were rejected as being unpatentable over Schramm et al. (5,935,864) in view of Nason (4,978,504) and further in view of Liotta et al. (5,942,407).

Page 3, lines 3-12: The Action states "*Schramm teaches a method and kit for collecting samples of liquid specimens for analytical testing. The device is best shown in Figures 2, 4 and 5. The device includes a sample container (5) with an open top (9) and lower capillary end (4), an immunoassay test strip (12) and a vial containing reagents and/or buffers and sealed with a penetrable foil. The lower end of the container has an inwardly extending portion (6) that forms an air-tight seal with the vial. Figures 3-5 show how the device is used. The process is described in column 4, lines 15-42. Capillary volume capacity is given in column 3, lines 29-31. Schramm does not teach a filter in the container, does not cite specific materials of construction, does not teach colorimetric analysis and does not teach a coated capillary*".

In response, applicant agrees with the Action, that Schramm on its own is distinguishable from the present invention because it lacks the following four elements:

- 1) a filter in the container
- 2) does not describe the materials of construction
- 3) does not teach colorimetric analysis, and
- 4) does not teach a coated capillary.

Page 3, line14 to page 4, line 6: *"Nason teaches a specimen test unit the test unit is best shown in Figures 12-15. The device includes to (14) and bottom caps ((60) containing a swab sampling element (20) in a housing (30). The housing includes a filter for filtering samples and reagents that flow into the housing and to the collection (bottom) vial. The housing is made of plastic to accommodate deformation (column 5, lines 58-62). Nason discloses colorimetric analysis on reaction products in a vial in column 9, lines 19-25 and column 10, lines 20-25. It would have been obvious to one of ordinary skill in the art to combine the cited features from Nason with the device of Schramm. One would use plastic in order to provide a deformable, yet resilient body structure. One would add the caps to seal the body structure. One would add the filters in order to filter mixed components, trap components and/or provide additional reagents as suggested by Nason (column 8, lines 5-15). One would perform colorimetric analysis on the contents of the test device in order to safeguard the operator from contact with samples and reagents (col. 9, lines 24-31). The combined teachings of Scramm and Nason do not teach a coated capillary."*

In response, applicant agrees in part and disagrees in part. In col. 5, lines 58-62, Nason describes that the housing is made of plastic. However, applicant is not arguing that this is the distinguishing feature because this is not a unique feature in the present invention.

Similarly, in col. 9, lines 19-25, Nason describes that the vial 70 is placed in a colorimetric device to measure the color change. However, applicant is not arguing that colorimetric measure of color change is unique in this invention. The color change in applicant's invention is recorded more easily, i.e., visually and does not require a device.

Moreover, the filter members 18 and 19 are serially mounted and filter 19 terminates in a rounded contour, col. 8, lines 5-15. Col 9, lines 24-31, cited in the Action, describe optical detection in a device without requiring the vial to be touched. These features are NOT present in the present invention and in fact distinguish it from Nason.

Applicant agrees with the Action that the combination of Schramm and Nason still does not teach the most unique feature of the invention – the coated capillary tube that is part of the collection device. In other words, there is no support to reject claims 1-15 based on Schramm in view of Nason. And this rejection should be withdrawn.

Page 4, lines 7- 16: *"Liotta et al. teaches an immunoassay device for determining analytes in a test sample. In discussing the signal-generating zone of the device, Liotta notes that it would be advantageous if the sample did not have any calcium present so it would be preferable to chelate the calcium with chelating agents. Liotta then goes on to state that the chelating agents could be added during dilution steps, incorporated into a sample collection device or coated onto a capillary pipette (column 12, lines 46-67). It would have been obvious to one of ordinary skill in the art to provide the chelating agent as a coating on the capillary. Schramm and Nason include an immunoassay device. One would add the chelating agents to the input capillary of Schramm and Nason in order to remove materials that would interfere with the immunoassay."*

In response, applicant disagrees because the cited section specifically states that "Specifically, an EDTA vacutainer or an EDTA coated capillary pipette could be utilized."

The present invention does not contain an EDTA vacutainer or EDTA coated capillary pipette. It contains a "chamber having a support means at the distal end and a filter membrane at the proximal end, wherein the capillary tube is volumetrically graduated and internally coated with an agent including a buffer, anticoagulant, detergent, stabilizer or a preservative". Therefore, as a matter of fact, there is no basis for Liotta to be relevant prior art. Moreover, Liotta employs aequorin as the photoprotein and requires a luminometer device for sensing light. These elements are NOT present in the present invention. There is no basis to support the rejection of claims 1-15 based on Schramm in view of Nason in view of Liotta. The rejection should be withdrawn.

Page 4, lines17-21: *"As for the graduated markings on the capillary, it would have been obvious to one of ordinary skill in the art to add markings for volume. Claim 12 recites a plurality of containers having color-coded identifiers. Providing a plurality of containers to perform a number of different tests would be obvious to one of ordinary skill in the art. More containers would allow for more tests."*

In response, applicant agrees, because there are no available plurality of containers having color-coded identifiers on the market. This means that hospitals have to use individually wrapped containers. This is expensive and inefficient—in other words, there is a need for more cost effective and convenient availability of specimen collecting devices packages together. Therefore, under Graham v. John Deere, Co 383 U.S. 1, 148 USPQ 459 (1966), this rejection should be withdrawn because the invention meets a current need and will reduce cost.

LEGAL STANDARD

As a matter of law, the above rejection under 35 USC §103 cannot be sustained. The Federal Circuit, has held that:

"The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention." Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 1986 MPEP 2141.

"To make a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." In re Vaeck 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (MPEP §2143 and 2142).

" When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper". Ex parte Skinner, 2 USPQ 1788 (Bd. Pat. App. & Inter. 1986).

In this regard, there is no teaching or suggestion whatsoever in Schramm/Nason/Liotta of improving a specimen collecting and analytical assembly by combining a) a one piece barrel container having an open top and a capillary tube with an open end, with a chamber disposed there between, b) the chamber having a support means at the distal end and a filter membrane at the proximal end, wherein the capillary tube is volumetrically graduated and internally coated with an agent

including a buffer, anticoagulant, detergent, stabilizer or a preservative, and, c) wherein the top of the barrel houses a vial containing a suitable reagent therein.

Therefore, as a matter of fact and law, there is no basis to sustain the rejections of any of the claims under consideration 1 through 15 as being obvious over Schramm in view of Nason and Liotta. This rejection should be withdrawn.

If for any reason, the Examiner should deem this application not in condition for allowance, the Examiner is respectfully requested to telephone the undersigned attorney to resolve any outstanding issues prior to issuing a further Office Action. Applicant will call the examiner to set up an interview with her and the Supervisory Patent Examiner.

Respectfully submitted,

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